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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,210	11/06/2002	Guy Leclerc	24900-501NATL	1816

7590 07/12/2006
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EXAMINER

LACYK, JOHN P

ART UNIT PAPER NUMBER

3735

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,210

Applicant(s)

LECLERC ET AL.

Examiner

John P. Lacyk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/16/02</u> . | 6) <input type="checkbox"/> Other: ____. |

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 8, 16-19, 30, 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "suitable conditions" in claims 1 and 16 is a relative term which renders the claim indefinite. The term "suitable conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In claim 8, "the radioactive molecule" lacks positive antecedent basis in that the claims do not previously recite that the molecule is radioactive. In claims 8 and 30 "conjugated polypeptides" should be "conjugated cationic polypeptides" to be consistent with the specification. The term "functionalized" in claims 48-49 is a relative term which renders the claim indefinite. The term "functionalized" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-7, 9-12, 16-17, 19-23, 29, 31-35 are rejected under 35

U.S.C. 102(b) as being anticipated by Bates et al (WO 98/17331).

Bates discloses an implantable medical device (10), such as a stent (12), which is coated with a layer of a bioactive material (18) on top of which there is a porous coating layer (20) (page 13, lines 11-15 and Figures 1 and 4). The base material (14) of the stent can comprise a variety of materials such as stainless, steel, nitinol, inconel, Au, Ta, Ti or alloys thereof (page 14, lines 14-26). The bioactive layer may contain a variety of compounds (see page 17, line 10- page 18, line 20) including a nitrate, dexamethasone sodium phosphate, deoxyribonucleic acid, an antisense nucleotide, peptides, proteins, iron chelators and any radioactive derivatives thereof (e.g. I131, P32, S36), and further including radiotherapeutic agents such as Co60, Ir192, P32, In111, Y90 and Tc99. The compounds listed include such being positively or negatively charged, especially in combination with a radioactive metal isotope, e.g. polyanionic complexes. A surface process can be carried out prior to deposition of layer 18, such as cleaning, solvent or plasma treatment (page 15, lines 27-31). The bioactive layer 18 may be applied by contacting the device with a fluid mixture of the bioactive material (page 30, lines 10-16) by dipping, which is considered to correspond to a "passive deposition method" or by electrostatic deposition. The fluid mixture can be a solution, e.g. made of dexamthosone or its derivatives and ethanol. The method of electrostatic deposition implies that there is an electrical potential difference applied between a surface to be covered and the fluid mixture or solution such that charged molecules are attracted by and thereby deposited onto the surface.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 8, 13-15, 18, 23-24, 30, 36-39, 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates et al in view of Eury (EP 0819446).

Bates et al, as discussed above, discloses a method for manufacturing a stent and a stent being covered by a layer of radioactive material, such as a β -emitter, and which is used to prevent restenosis. Eury discloses a stent having a radioisotope attached to the outer layer of the stent. Eury teaches using a gold base layer and Ir192 as the radioisotope and a chelator (column 5, lines 46-50). Eury teaches attaching a radioisotope to a Au layer by employing molecules which contain thiol-containing groups to bind the radioisotope. A modification of Bates et al to include a thiol containing group to attach the gold would have been obvious since this would have been another well known means for attaching a layer to the stent.

8. Claims 24-28 and 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bates et al in view of Eury as applied to claims above, and further in view of LeClerc et al (WO 98/23299).

LeClerc et al discloses the use of and making of a radioisotope-labelled oligonucleotides for preventing restenosis. The oligonucleotide can be a double or a

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single stranded DNA sequence and teaches a 15-mer DNA oligonucleotide (page 13, lines 13-15) and using a β -emitter, preferably P32 (page 13, lines 32-33). Therefore a modification of Bates et al to include a radioisotope-labelled oligonucleotide would have been obvious in view of the teachings of LeClerc et al which shows the advantages of radiolabeled DNA carriers for treating restenosis.

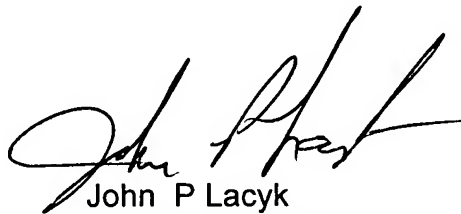
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hafeli et al and Kraus et al are cited to further show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is 571-272-4728. The examiner can normally be reached on Mon-Fri, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



John P Lacyk
Primary Examiner
Art Unit 3735

J.P. Lacyk